

(b) *Sponsor*. See No. 033392 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See §§ 556.200 and 556.510 of this chapter.

(d) *Conditions of use*. *Dairy cows*—(1) *Amount*. One syringe per quarter at the last milking prior to drying off.

(2) *Indications for use*. Intramammary use to reduce the frequency of existing infection and to prevent new infections with *Staphylococcus aureus* in dry cows.

(3) *Limitations*. Not to be used within 6 weeks of freshening. Not for use in lactating cows. Milk taken from animals within 96 hours (8 milkings) after calving must not be used for feed. Animals infused with this drug must not be slaughtered for food within 60 days from the time of infusion nor within 96 hours after calving. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

**§ 526.1696d Penicillin G procaine-novobiocin for intramammary infusion.**

(a) *Specifications*. For lactating cattle: each 10-milliliter dose contains 100,000 units of penicillin G procaine and 150 milligrams of novobiocin as novobiocin sodium. For dry cows: 200,000 units of penicillin G procaine and 400 milligrams of novobiocin as novobiocin sodium.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Lactating cows*—(i) *Amount*. 10 milliliters in each infected quarter after milking. Repeat once after 24 hours.

(ii) *Indications for use*. Treating lactating cows for mastitis caused by susceptible strains of *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(iii) *Limitations*. For udder instillation in lactating cattle only. Do not milk for at least 6 hours after treatment; thereafter, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food for 15 days following the latest treatment. If redness, swelling, or abnormal milk persists,

discontinue use and consult a veterinarian.

(2) *Dry cows*—(i) *Amount*. 10 milliliters in each quarter at time of drying off.

(ii) *Indications for use*. Treatment of subclinical mastitis caused by susceptible strains of *Staphylococcus aureus* and *Streptococcus agalactiae*.

(iii) *Limitations*. For udder instillation in dry cows only. Do not use less than 30 days prior to calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Treated animals must not be slaughtered for food for 30 days following udder infusion.

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

**§ 526.1810 Pirlimycin hydrochloride.**

(a) *Specifications*. Each 10-milliliter syringe contains 50 milligrams of pirlimycin (as pirlimycin hydrochloride).

(b) *Sponsor*. See 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.515 of this chapter.

(d) *Conditions of use*. (1) *Dose*. 50 milligrams in each infected quarter, repeated once after 24 hours.

(2) *Indications for use*. For lactating dairy cattle for the treatment of clinical and subclinical mastitis caused by *Staphylococcus* species, such as *Staphylococcus aureus*; and *Streptococcus* species, such as *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(3) *Limitations*. Milk taken from animals during treatment and for 36 hours following the last treatment must not be used for food. Treated animals must not be slaughtered for food use for 9 days following the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 58486, Nov. 2, 1993, as amended at 65 FR 61091, Oct. 16, 2000]

**PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS**

Sec.  
529.40 Albuterol.

## § 529.40

- 529.50 Amikacin sulfate intrauterine solution.
- 529.400 Chlorhexidine tablets and suspension.
- 529.469 Competitive exclusion culture.
- 529.1003 Flurogestone acetate-impregnated vaginal sponge.
- 529.1030 Formalin.
- 529.1044 Gentamicin sulfate in certain other dosage forms.
- 529.1044a Gentamicin sulfate intrauterine solution.
- 529.1044b Gentamicin sulfate solution.
- 529.1115 Halothane.
- 529.1186 Isoflurane.
- 529.1526 Nifurpirinol capsules.
- 529.1660 Oxytetracycline.
- 529.1940 Progesterone intravaginal inserts.
- 529.2090 Salicylic acid.
- 529.2150 Sevoflurane.
- 529.2464 Ticarcillin powder.
- 529.2503 Tricaine methanesulfonate.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13881, Mar. 27, 1975, unless otherwise noted.

## § 529.40 Albuterol.

(a) *Specifications.* A net weight of 6.7 grams of formulated albuterol sulfate is supplied in a pressurized aluminum canister within an actuator system equipped with a detachable nasal delivery bulb.

(b) *Approvals.* See No. 000010 in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use—(1) Amount.* Each valve actuation (puff) of the device delivers 120 micrograms (mcg) of albuterol sulfate. One dose is three (3) puffs, totaling 360 mcg.

(2) *Indications for use.* For the immediate relief of bronchospasm and bronchoconstriction associated with reversible airway obstruction in horses.

(3) *Limitations.* Not for use in horses intended for food.

[67 FR 7072, Feb. 15, 2002]

## § 529.50 Amikacin sulfate intrauterine solution.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 250 milligrams of amikacin (as the sulfate).

(b) *Sponsor.* See No. 000856 and 059130 in § 510.600(c) of this chapter.

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(c) *Conditions of use—(1) Amount.* Two grams (8 milliliters) diluted with 200 milliliters of sterile physiological saline per day for 3 consecutive days.

(2) *Indications for use.* For treating genital tract infections (endometritis, metritis, and pyometra) in mares when caused by susceptible organisms including *E. coli*, *Pseudomonas* spp., and *Klebsiella* spp.

(3) *Limitations.* For intrauterine infusion in the horse only. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 9640, Mar. 8, 1983, as amended at 53 FR 27852, July 25, 1988; 62 FR 15110, Mar. 31, 1997; 62 FR 23358, Apr. 30, 1997]

## § 529.400 Chlorhexidine tablets and suspension.

(a) *Specification.* Each tablet and each 28-milliliter syringe of suspension contain 1 gram of chlorhexidine dihydrochloride.<sup>1</sup>

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* Place 1 or 2 tablets deep in each uterine horn; or infuse a solution of 1 tablet dissolved in an appropriate amount of clean boiled water; or infuse one syringe of suspension into the uterus.<sup>1</sup>

(2) *Indications for use.* For prevention or treatment of metritis and vaginitis in cows and mares when caused by pathogens sensitive to chlorhexidine dihydrochloride.<sup>1</sup>

(3) *Limitations.* Prior to administration, remove any unattached placental membranes, any excess uterine fluid or debris, and carefully clean external genitalia. Use a clean, sterile inseminating pipette for administering solutions and suspensions. Treatment may be repeated in 48 to 72 hours.<sup>1</sup>

[43 FR 10705, Feb. 23, 1979]

## § 529.469 Competitive exclusion culture.

(a) *Specifications.* Each packet of lyophilized culture contains either

<sup>1</sup>These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.